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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/692,474 | 10/22/2003 | Pamela Cifra | 020154-001210US | 7244 |

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| EXAMINER | |
|---|---|
| PRONE, CHRISTOPHER D | |
| **ART UNIT** | **PAPER NUMBER** |
| 3738 | |
| **MAIL DATE** | **DELIVERY MODE** |
| 05/21/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/692,474 | CIFRA ET AL. | |
| | Examiner | Art Unit | |
| | Christopher D. Prone | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-56,58-60 and 62* is/are pending in the application.

4a) Of the above claim(s) *1-50,55 and 56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-54 and 57-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51-54, and 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogle (6,113,636). Ogle discloses a device comprising: at least one implantable medical device; and at least one zinc-salt (e.g. zinc nitrate col. 7, lines 15-29) containing component coupled with the device, e.g. a graft (col. 5, lines 40-51) in a concentration between 1.0 picomolar and about 500 millimolar (e.g. col. 7, lines 58-66).

Please note that the present specification discloses:

> Devices, zinc-containing components, and means for coupling devices and zinc are typically selected to provide for the release of ionic zinc from the device at a location to have a desired effect on a tissue or similar substance. For example, devices used in various embodiments of the present invention may be made by various known techniques, such as those described in U.S. Pat. Nos. 6,113,636, 6,190,407, 6,267,782 and 6,322,588, the complete contents of which are hereby incorporated by reference. Such techniques involve depositing a metal or compound, such as zinc or a zinc compound on the surface of a device (for instance a stent or implant) formed from a suitable biocompatible material such as stainless steel, titanium, nitinol, ceramics, polytetrafluoroethylene, silastic, polylactide, polyglycolide, polylactide-co-glycolide, and the like, acrylates, methacrylates, polyurethane, or combinations of these. Other biocompatible materials or compounds may similarly be used in such devices. Deposition may be carried out either on a device already formed or on biocompatible material that will subsequently be used for production of such a device. The deposition is carried out by techniques such as incubation of the device or biocompatible material with a solution of a zinc salt, as described in U.S. Pat. No. 6,113,636. Alternatively, the zinc may be deposited on the device or biocompatible material in the form of elemental zinc. U.S. Pat. No. 6,113,636 describes processes for producing such a zinc-containing material, including chemical reduction, photochemical reduction, and electrodeposition or

electroplating. Also, as described in that patent, a combination of elemental zinc and a zinc salt may be deposited on the material.

The graft of Ogle is made by the same method and the same materials as the present invention as admitted by the present specification and therefore has the same properties, e.g. plaque inhibition, as that which are claimed.

Claims 51 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Tam et al. (6,261,320). Tam et al. discloses a device comprising: at least one implantable medical device (e.g. Fig. 10); and at least one zinc- containing component (e.g. column 27, line 53- col. 28, line 17) coupled with the device, wherein the zinc-containing component is primarily on a tissue-facing surface (col. 31, lines 21-32).

***Response to Arguments***

Applicant's arguments filed 3/16/07 have been fully considered but they are not persuasive. The applicant argues that both Ogle and Tam fails to disclose a zinc-containing component that is selectively deposited over a portion of the device. In regards to Ogle in the admitted prior art disclosed above it is well known to provide a zinc coating on the device of Ogle. In regards to the Tam reference the reference teaches that the coating may inhibit migration. Therefore it is inherent that at least a small amount will be leaked.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738

CDP

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700